

**PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

Docket No: Q88294

Hiroshi TSUCHITA, *et al.*

Appln. No.: 10/537,401

Group Art Unit: 1656

Confirmation No.: 1465

Examiner: Marsha M TSAY

Filed: November 21, 2005

For: SUSTAINED IMPROVER OF MUSCULAR FATIGUE

DECLARATION UNDER 37 C.F.R. § 1.132

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Masayuki Suzuki, hereby declare and state:

I am a citizen of Japan;

I have received the degree of Master of Agricultural Science in 1991 from Tokyo
University of Agriculture;

I have been employed by Meiji Dairies Corporation since 1991, where I hold a position as
manager, with responsibility for product development of sports nutrition;

I am familiar with the subject matter disclosed by the present application as well as the
Office Action dated June 9, 2010 and the Advisory Action dated September 20, 2010.

I note that the Examiner asserts in the Office Action that one skilled in the art would have
been motivated to delete carnitine from the composition taught by Brantman, because Soop
concludes, based on one time experiments with and without carnitine supplement, that

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endogenous carnitine is produced in the body and carnitine is maintained at an adequate level during exercise, and that carnitine supplement has no substantial effect on skeletal muscle metabolism under normal physiological conditions.

In this regard, I believe that that one skilled in the art would not have been motivated to remove carnitine from Brantman composition, instead would have been taught away from deleting carnitine, from reading scientific articles published before or around the invention of present application.

Brantman clearly teaches, at col. 3, line 55 to col. 4, line 30, the use of carnitine in his composition and the object of the use of carnitine is to optimize skeletal muscle function in relation to oxidation of fatty acids for calories; to the oxidation of branched amino acids (BAAs); and to enhance the removal of toxic ammonia.

Further, Brantman teaches that the objects of the invention are realized by a careful selection of specific amino acids to be added to whole protein and other nutrients, so as to achieve a diet which is enriched with specific amino acids (carnitine, glutamine, isoleucine, leucine and valine), in order to maximize protein synthesis in skeletal muscle (col. 4, lines 25-30).

Although Soop *et al.* teaches that carnitine supplementation has no substantial effect on skeletal muscle metabolism under normal physiological conditions, Soop *et al.*'s study relates to the single use of carnitine and its effect on skeletal muscle metabolism under normal physiological conditions.

In contrast, Brantman teaches that "This invention relates to compositions of specific nutrients to facilitate the adaptation of skeletal muscle to programs of strenuous exercise."

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Thus, one skilled in the art would not consider the conclusion by Soop *et al.* as being conclusive or sufficient to motivate to omit cartinine from the composition of Brantman.

Further, I reviewed three publications which were published after Brantman (1987) and Soop *et al.* (1988) but before 2003, when the instant application was filed:

Arenas J. *et al.*, "Carnitine in muscle, serum, and urine of nonprofessional athletes: effects of physical exercise, training, and L-carnitine administration," *Muscle Nerve* 1991, 14, 598-604;

Huertas R. *et al.*, "Respiratory chain enzymes in muscle of endurance athletes: effect of L-carnitine," *Biochem. Biophys. Res. Commun.*, 1992, 188, 102-107; and

Arenas J., *et al.*, "Effects of L-carnitine on the pyruvate dehydrogenase complex and carnitine plamitoyl transferase activities in muscle of endurance athletes," *FEBS Lett.*, 1994, 341,91-93.

The three publications teach that carnitine amount in muscle decreases in athlete during 1 to 6 months training (*Muscle Nerve* 1991, 14, 598-604); that decrease in amount of carnitine in muscle can be prevented according to training by supplementation of carnitine (*Muscle Nerve* 1991, 14, 598-604); and that activities of enzymes in muscle which become key enzymes (such as puruvate dehydrogenase and electron transport chain enzymes) can be increased (*Biochem. Biophys. Res. Commun.*, 1992, 188, 102-107 and *FEBS Lett.*, 1994, 341,91-93).

Apparently, these publications show that carnitine is not maintained at an adequate level during exercise, contrary to the teaching of Soop *et al.*

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Therefore, one skilled in the art, who reads Brantman, Soop, and the above three references, would rather have been persuaded to maintain carnitine in Brantman composition to attain its desired effects.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: November 11, 2010.

Masayuki Suzuki
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